

## REMARKS

As an initial matter, the Applicants would like to thank Examiners Christopher Stone and Ardin Marschel for the interview conducted on August 4, 2008. The topics of discussion are disclosed in these remarks.

Claims 19-27 are currently pending.

Claim 19 has been amended, support for the amendment may be found at least in the specification, examples, and figures as originally filed. No new matter is believed or intended to be involved.

Claims 22, and 25 have been amended merely to clarify the invention. All of the amendments are fully supported by the specification, claims, and figures as originally filed. No new matter is believed or intended to be involved.

Claim 35 has been added, support for the new claim may be found at least at, for example in paragraph [0141] of the Specification as originally filed. No new matter is believed or intended to be involved.

### **Rejection under 35 U.S.C. § 112**

The Examiner rejected claim 21 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. This contention is respectfully traversed.

As discussed in the Examiner interview, the Applicant pointed out that the specification does provide written support for prodrugs, as shown at least in paragraphs [0013], [0014], and [0175]-[0188]. Even without the description in these listed paragraphs, the application is enabling because the Office indicated that drugs and vaccines meets the written description and enablement provisions. A person of ordinary skill who is knowledgeable about drugs and vaccines would also be knowledgeable about prodrugs. The description of derivatives and

analogs is inherent as a person of ordinary skill who is knowledgeable about drugs and vaccines would also be knowledgeable about derivatives and analogs of drugs, vaccines, and prodrugs.

During the interview, the Examiners indicated that the information traversed the 35 U.S.C. § 112, first paragraph rejection. Accordingly, the Applicant respectfully requests withdrawal of the rejection of claim 21.

The Examiner rejected claim 22 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter. Due to amendment to claim 22, this rejection is moot.

Accordingly, the rejections under 35 U.S.C. §112, second paragraph, have been traversed and removal of the objections is respectfully requested.

#### **Rejection under 35 U.S.C. § 102**

The Examiner rejected claims 19-22 under 35 U.S.C. 102(b) as being anticipated by CUBICCIOTTI (US 2002/0034757). The Examiner contends that CUBICCIOTTI discloses a method of delivering an agent or agents (drugs) to a subject comprising administering a composition comprising a host-rotaxane/agent(s) complex. This contention is respectfully traversed.

As discussed in the Examiner interview, the Applicant pointed out that CUBICCIOTTI does not provide an enabling disclosure. For a reference to constitute an anticipatory reference, it must be an enabling disclosure by disclosing enough to allow one of ordinary skill in the art to practice what is claimed. Regarding rotaxanes, CUBICCIOTTI only makes broad statements about combining classes of molecules without describing them or how to combine them. CUBICCIOTTI suggests a multimolecular drug delivery system comprising both receptor-targeted prodrugs and tethered prodrug delivery configurations, see [0042]. The multimolecular drug delivery system may be pseudoirreversibly conjugated to a biological or biocompatible substance or immobilized to a biological or biocompatible solid support, see [0175]. A pseudoirreversible attachment may be achieved by a rotaxane, see [0244]. The applicant has been unable to find, and the Examiner has not further pointed out, any other details about the use of rotaxane in CUBICCIOTTI. Because CUBICCIOTTI does not teach about how a rotaxane

may be attached to a drug delivery system it is not enabling and cannot be used as an anticipatory reference.

Even if CUBICCIOTTI is considered to enable the genus it describes, *a multimolecular drug delivery system comprising both receptor-targeted prodrugs and tethered prodrug delivery configurations that may be pseudoirreversibly conjugated to a biological or biocompatible substance, where the pseudoirreversible attachment is a rotaxane*, it does not anticipate the species claimed in amended claim 19. The only mention of rotaxanes is for polymeric ones as shown in paragraph [0244], “Pseudoirreversible attachment may also be achieved by threading a ring-shaped or circular molecule (e.g., a rotaxane) with a linear molecule (e.g., a polymer with knotted or bulky ends)....” The disclosure of a genus in the prior art does not always anticipate a species within that genus. The applicants have amended claim 19 to more clearly point out the claimed subject matter. The host-rotaxane species, those that are not polymeric, is a species that cannot be anticipated by the genus described in CUBICCIOTTI.

During the interview, the Examiners indicated that the amendment to claim 19 traversed the 35 U.S.C. § 102 rejection. Consequently, CUBICCIOTTI does not anticipate any of the of the amended or dependent claims, nor does it make obvious any of the claims in combination with any of the references cited by the Examiner. Reconsideration and allowance of all pending claims is respectfully requested.

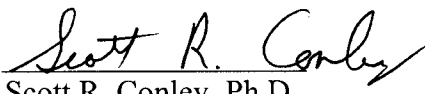
#### **Rejection under 35 U.S.C. § 103**

The Examiner rejected claims 23-27 under 35 U.S.C. 103(a) as being anticipated by CUBICCIOTTI (US 2002/0034757) in view of Goodman and Gilman's, The Pharmacological Basis of Therapeutics. The Examiner contends that it would have been obvious to one of ordinary skill in the art to administer the composition via any conventional route of administration in conjunction with a conventional carrier system appropriate for said route. This contention is respectfully traversed.

Because claim 19 should be allowable, as discussed above, the claims dependent upon claim 19, claims 23-27 should also be allowable. Reconsideration and allowance of all pending claims is respectfully requested.

Based on the foregoing, all pending claims are in a condition for allowance. Accordingly, Applicant respectfully requests reconsideration and an early notice of allowance. Should the Examiner wish to discuss the amendments or arguments made herein, Applicant invites the Examiner to contact the undersigned at (513) 651-6818 or via e-mail at [srconley@fbtlaw.com](mailto:srconley@fbtlaw.com).

Respectfully submitted,  
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